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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,592	03/11/2004	Robert A. Herrmann	00-0193US02	6360

27774 7590 04/15/2009

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,592	HERRMANN ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *23-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22, 40-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 02/02/2009.

Claims 1-39 previously presented. Claims 40 and 41 have been added.

Claims 23-39 are withdrawn from further consideration as being drawn to a nonelected inventions and species. Election was made **without** traverse in the reply filed on 08/22/2007.

Claims 1-22 40 and 41 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/02/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-22 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,087,479 ('479) combined with the article "S-Nitrosothiols cause prolonged, nitric oxide mediated relaxation in human saphenous vein and internal mammary artery: therapeutic potential in bypass surgery" by Sogo et al.

US '479 teaches a medical device that may be made such that at least a portion of it which come in contact with blood or vascular tissue includes nitric oxide adduct (col.9, lines 48-52). The nitric oxide adduct can be incorporated into synthetic or natural

matrix which is then used to coat those same contact surfaces of the device (col.9, lines 57-60). Therefore, the nitric oxide adduct can be incorporated in portion of the vascular device and also in the coating of the same device, i.e. two different matrices, which are expected to be different. The nitric oxide adducts include S-nitosylated compounds such as nitrosylated amino acid, sydnonimines, and organic nitrate (col.5, lines 1-5, 18-22; col.10, lines 41-56). The polymeric matrix includes polylactic acid (col.3, line 65-col.4, line 15; col.9, lines 57-59; col.10, lines 1-2). The reference disclosed that the material of the medical device different from the coating matrix. The medical devices of the invention can be vascular devices, such as catheter, heart valve (col.3, lines 59-62).

Although the reference teaches many different nitric oxide adducts and teaches inclusion of nitric oxide adduct in portion of the device as well as in the coating, the reference does not explicitly teach including two different nitric oxide donors in the same device.

Sogo et al. teach that S-nitroso-N-acetyl-D,L-penicillamine and S-nitrosoglutathione produce more relaxation of vessel walls than commonly used NO donors, and more specifically, teach that the relaxation caused by S-nitroso-N-acetyl-D,L-penicillamine was more sustained, and S-nitrosoglutathione selectively dilates human arteries in vitro and in vivo, and their use might improve the outcome of coronary artery bypass (page 1237, left col.; page 1241, right col.; page 1243, left col.).

Therefore, Sogo et al. recognized administration of two different nitric oxide donors simultaneously, and US '479 recognized inclusion of two nitric oxide donors in single device in different portions, e.g. device itself and its coating.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide vascular medical device comprising more than one NO donor compounds included in portion of the device and in coating of the same device as disclosed by US '479, and select S-nitroso-N-acetyl-D,L-penicillamine and S-nitrosoglutathione disclosed by Sogo et al. to be included in the same device. One would have been motivated to do so because Sogo et al. teach that combination of these two NO donor compounds produce more relaxation of vessel walls than commonly used NO donors with prolonged sustained relaxation and dilatation of human arteries, and their use might improve the outcome of coronary artery bypass. One would have reasonably expected formulating vascular medical device comprising S-nitroso-N-acetyl-D,L-penicillamine and S-nitrosoglutathione, one is incorporated in a portion of the vascular device and one in the coating of the device to successfully provides prolonged sustained relaxation and dilatation of human arteries, with improvement on the outcome of coronary artery bypass.

The combination of the references teaches the same first nitric oxide donor and second nitric oxide donor as instantly claimed, therefore, the half-life, activity, release rates, and susceptibility to metal ion catalyst release are expected to be the same as those recited by the instant claims.

Regarding claims 40 and 41, it is expected that that the release of the nitric oxide to be faster in circulating blood than to the vascular tissue.

Response to Arguments

5. Applicant's arguments with respect to claims 1-22 and 40-41 have been considered but are moot in view of the new ground(s) of rejection.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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